Recombinant DNA Advisory Committee Submission
BB IND 8559
Protocol Number TG4010.01
Protocol Title: Phase I Bridging Trial of TG4010 as Antigen-Specific Immunotherapy in Patients with MUC1 Positive Advanced Cancer

Non-Technical Abstract

This study involves the use of an experimental product, TG4010. The purpose of the study is to determine TG4010 can stimulate the body's immune system to help it fight the cancer. Patients with advanced cancer whose tumor is MUC-1 positive and is not curable with standard anti-cancer therapy may be eligible to enroll into this study. The experimental product, TG4010, is a modified vaccinia virus (used in smallpox vaccinations) into which two (2) genes have been placed. One gene is for a protein (MUC1) found in cancer cells. The second gene is for human interleukin 2 (IL2) which the body's immune system makes to help it fight cancer. The TG4010 is given as a shot in the muscle of the arm once every a week for four (4) weeks. If the therapy is working, it can be continued every other week for the next 2 months, then every 4 weeks for as long as it is tolerated. Two different doses of TG4010 will be tested. The first three patients will receive the lower dose, 5×10^6 pfu. If all three patients tolerate that dose, the next three patients will be entered into the study and will receive the higher dose, 5×10^7 pfu. Blood tests will be taken throughout the study to assess the safety of the treatment and its effect on the immune system. Blood and urine samples will be taken during the first 6 weeks of the study to determine if the virus spreads to other parts of the body. Scans and x-rays will be taken as necessary for the normal care and treatment of the patients.